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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,211	08/24/2001	Daniel Lootz	7040-40	3319

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EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,211

Applicant(s)

LOOTZ ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 24-104 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 24 and 27-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Applicant's election with traverse of invention I in Paper No. 10 is acknowledged. The traversal is on the ground(s) that it is not clear to applicant how the stent can go from a non-expanded state to a fully-expanded state without passing at least ephemerally through a partially-expanded state. This is not found persuasive because the stent of invention I could be implanted without performing the checking step (while the stent is in the partially expanded state) as well as the correction step defined in claim 25. The requirement is still deemed proper and is therefore made FINAL.

Claims 25 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Applicant is advised that should claim 3 be found allowable, claim 27 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Applicant is advised that should claim 12 be found allowable, claim 65 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in

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wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the device for producing relative movement of the sheathing device in the first direction and the device for producing relative movement of the sheathing device in the second direction must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear what the device for producing relative movement of the sheathing device in the first direction and the device for producing relative movement of the sheathing device in the second direction is and how these devices

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interact with the sheathing device without interfering with one another.

Claims 1-21, 24 and 27-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, line 1, it is unclear what is meant by "a peripheral stent". The preamble of claim 1 indicates that a stent is claimed. However, the body of the claim appears to include the sheathing (which is not part of the stent) as part of the claimed combination ("a sheathing that bears at least in a portion-wise manner thereagainst") making the preamble inconsistent with the body of the claim. In claim 1, it is unclear what the "first direction" is. It appears that the claim inaccurately defines the first direction as the direction that the sheathing bears against the stent (i.e. the radial direction). The sheathing defined in claim 2 has already been claimed in claim 1, resulting in a double recitation of the same element. In claim 4, lines 4-6 are not understood. For example, it is unclear what is "projecting in the first direction". In claim 5, lines 2-3, it is not seen how the first and second annular portions are adjacent in the first direction (which appears to be a radial direction since it is defined in claim 1 as the direction in which sheathing bears

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against the stent. Sheathing 9 bears against the stent in a radial direction to compress it.). Other claims have a similar problem. Also, in claim 5, line 4 and other claims, it is unclear what the "peripheral direction" is. Claim 11 is confusing and is not understood. For example, it is unclear what "individually or in a portion-wise manner" means. As to claim 12, the annular support portions and bar elements have already been defined in claim 1, resulting in a double recitation of the same element. Other claims which have identical language to all of the above mentioned claims are similarly unclear. In claim 24, line 10, there is no antecedent basis for "the first direction". Also, the device for producing relative movement of the sheathing device in the first direction is defined as being different from the device for producing relative movement of the sheathing device in the second direction. However, it is unclear from the disclosure if this is in fact the case.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of

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section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 9-15, 24, 27-35, 44, 50, 51, 57, 58, 64, 65, 67, 68, 70, 71, 74-77 and 81 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Duerig et al. (6,190,406). Duerig et al. disclose a plurality of annular support portions 52 comprising bar elements, connecting bars 70 and sheathing 40. There is inherently no hooking engagement between the stent and sheathing when the

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sheathing is retracted. Alternatively, it would have been obvious that there is no hooking engagement between the stent and sheathing when the sheathing is retracted since there is nothing that would permit such hooking. As to claims 10 and 11, note col. 7, lines 39-60 of Duerig et al. As to claims 12-14, the Duerig et al. sheathing is inherently capable of being pushed back over the stent after it is only slightly retracted. As to claim 24, Duerig et al. disclose a device 22 for holding the stent during relative movement between the sheathing device and the stent.

Claims 7, 8, 36-43, 45-49, 52-56, 59-63, 66, 69, 72, 73, 79, 80, 83, 84, 87, 88, 91, 92, 97, 98, 103 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (6,190,406) in view of Cox (6,461,380). Duerig et al. fail to disclose connecting bars 7 engaging a central region of the annular support portion. However, Cox teaches that connecting bars 28 between annular support portions 18 of a stent should be connected to the annular support portions 18 in a central region of the bar element 32 between the turning points (apexes) of the bar element so that it avoids the highly stressed apex area (col. 3, lines 45-50 and col. 2, lines 46-49). It would have been obvious to so connect the Duerig et al. connecting bars 7 so that it too would have this advantage. Note that the Cox connecting points between

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the connecting bars 28 and the bars of the annular support portions 18 are both near a turning point of the annular support portion as defined in claim 5 (and at the end of the turning point itself such that the connecting point engages the turning point as defined in claim 6, noting that the "turning point" is considered to be the entire curved portion near the apex) and at a central region of the bar element as defined in claims 7 and 8. As to claims 80 and 84, Duerig et al. fail to disclose the stent material in a stress-induced martensitic state at body temperature. However, it was well known in this art to design make shape memory alloys such that they are in a stress-induced martensitic state at body temperature in order to facilitate entry into the patient's body. It would have been obvious to make the Duerig et al. the stent material in a stress-induced martensitic state at body temperature so that it too would have this advantage. As to claim 91, the width of the Duerig et al. bar element varies over the length thereof (col. 6, lines 8-39). As to claim 97, the center line of the Duerig et al. bar element is in the shape of an elliptical arc in the region of the turning points when the stent is expanded, as seen in figure 5, for example.

Claims 16-18, 78, 82, 85, 86, 89, 90, 94, 95, 100 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig

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et al. (6,190,406). Duerig et al. fail to disclose the stent material in a stress-induced martensitic state at body temperature. However, it was well known in this art to design make shape memory alloys such that they are in a stress-induced martensitic state at body temperature in order to facilitate entry into the patient's body. It would have been obvious to make the Duerig et al. the stent material in a stress-induced martensitic state at body temperature so that it too would have this advantage.

Claims 19-21, 93 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (6,190,406) in view of Lau et al. (6,015,429). Duerig et al. fail to disclose a direction of curvature changing in the central region of the bar element. However, Lau et al. teach that the central region of a meandering bar element of a stent may be curved (at 114 in figure 1C) instead of straight (at 106 in figure 1A). This shape has the self-evident advantage of providing more support to the blood vessel along the edges of the meandering bar element. It would have been obvious to incorporate this shape into the Duerig et al. bar element so that it too would have this advantage. Note that the direction of curvature changes at 114 in figure 1C.

Claims 96 and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (6,190,406) in view of Cox

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(6,461,380) as applied to claims 80 and 84 above, and further in view of Lau et al. (6,015,429) for the reasons set forth in the paragraph above.

Claims 1-21, 24 and 27-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 09/939,057. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences in scope involve only minor, obvious differences.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
September 5, 2003



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731